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IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

IN RE: '318 PATENT INFRINGEMENT LITIGATION	)	C.A. No. 05-356-KAJ (consolidated)

REQUEST FOR JUDICIAL ASSISTANCE FOR THE PURPOSE OF OBTAINING EVIDENCE AND ORAL EXAMINATIONS UNDER OATH PURSUANT TO THE HAGUE CONVENTION OF 18 MARCH 1970 ON THE TAKING OF EVIDENCE ABROAD IN CIVIL OR COMMERCIAL MATTERS (BOEHRINGER INGELHEIM GMBH AND CO. KG)

From the People of the United States of America, to the Central Authority - Rhineland-Palantinate, Das Ministerium der Justiz, Ernst-Ludwig-Strasse 3, 55116 Mainz, Germany,

GREETINGS:

1.	Sender	United States District Court District of Delaware J. Caleb Boggs Federal Building 844 N. King Street Wilmington, DE 19801 United States of America
2.	Central Authority of the Requested State:	Central Authority - Rhineland-Palantinate Das Ministerium der Justiz Ernst-Ludwig-Strasse 3 55116 Mainz, Germany
3.	Person to whom the executed request is to be returned:	ASHBY & GEDDES Steven J. Balick (Delaware Bar No. 2114) John G. Day (Delaware Bar No. 2403) 222 Delaware Avenue 17th Floor P.O. Box 1150 Wilmington, DE 19899 Telephone: 302-654-1888 Facsimile: 302-654-2067 Email: sbalick@ashby-geddes.com jday@ashby-geddes.com

4. Specification of the date by which the requesting authority requires receipt of the response to the Letter of Request

Date: June 14, 2006

IN CONFORMITY WITH ARTICLE 3 OF THE CONVENTION, THE UNDERSIGNED APPLICANT HAS THE HONOR TO SUBMIT THE FOLLOWING REQUEST:

5.	a.	Requesting Judicial Authority:	United States District Court District of Delaware J. Caleb Boggs Federal Building 844 N. King Street Wilmington, DE 19801
	b.	To the competent authority of the	Central Authority - Rhineland-Palantinate Das Ministerium der Justiz Ernst-Ludwig-Strasse 3 55116 Mainz, Germany
	c.	Name of the case and any identifying number	In re: '318 Patent Infringement Litigation, C.A. No. 05-356-KAJ (consolidated)
6.	Names and addresses of the parties and their representatives:		
	a.	Plaintiffs:	Janssen Pharmaceutica N.V. Turnhoutseweg 30 2340 Beerse, Belgium Janssen, L.P. 1125 Trenton Harbourton Road PO Box 200 Titusville, NJ 08560 Synaptech, Inc., P.O. Box 157 Cold Spring Harbor, NY 11724 <u>Representatives</u>: Steven J. Balick John G. Day ASHBY & GEDDES 222 Delaware Avenue 17th Floor

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b. Defendants:

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2) Mylan Pharmaceuticals Inc.
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5) Dr. Reddy's Laboratories, Inc.
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7.	a.	Nature of the Proceedings (divorce, paternity, breach of contract, product liability, etc.)	This consolidated action is for patent infringement arising under the patent laws of the United States, Title 35 of the United States Code, for infringement of United States Patent No. 4,663,318 ("the '318 patent") attached hereto as Exhibit 1.

b.	Summary of Complaint	Plaintiffs are exclusive licensees under the '318 patent, pursuant to an exclusive license agreement between Synaptech and Ms. Bonnie M. Davis, Ph.D, Janssen Pharmaceutica N.V., and Janssen Pharmaceutica Products, L.P., of the right to make, use and sell certain pharmaceutical preparations containing galanthamine hydrobromide to treat Alzheimer's Disease in the United States and other territories. Pursuant to that exclusive license, Plaintiffs currently market galanthamine hydrobromide tablets under the trademark RAZADYNE®. Until 2005, Plaintiffs market galanthamine hydrobromide tablets for the purpose of treating Alzheimer's disease under the trademark REMINYL®. As exclusive licensees, Plaintiffs are authorized to enforce the '318 patent. Defendants submitted Abbreviated New Drug Applications (ANDAs) to the Food and Drug Administration seeking approval to engage in the commercial manufacture, use, offer for sale and sale of galanthamine hydrobromide tablets before the expiration of the '318 patent. Plaintiffs seek judgment declaring that the making, using, selling, offering to sell, or importing of the galanthamine hydrobromide described Defendants' ANDAs constitute infringement of the '318 patent, or inducing or contributing to such conduct.
c.	Summary of defense and counterclaim.	On December 2, 2005, the parties entered into a Stipulation Not to Contest Infringement of the asserted claims of the '318 patent (claims 1 and 4). Defendants continue to assert that these claims are invalid. For example, Defendants contend that the asserted claims of the '318 patent are obvious to one of ordinary skill in the art and/or anticipated by prior art (prior published work) and seek as counterclaims judgment of invalidity of the asserted claims of the '318 patent.
d.	Other necessary information or documents	To establish validity of a patent, U.S. law requires the courts to consider objective considerations of non-obviousness to establish that the patent was not obvious. These objective considerations of nonobviousness include skepticism of the invention by those who rejected opportunities to license the invention based on a belief that it was not effective and

			the long felt need by the community and companies for the invention.
8.	a.	Evidence to be obtained or other judicial act to be performed:	1) The names of all persons employed by Boehringer Ingelheim KG who were involved in any evaluation, consideration of discussion to license, market or develop the '318 patent or a '318 patent product. 2) The names and responsibilities of all persons employed by Boehringer Ingelheim KG who were involved in any evaluation, consideration, or discussion of galanthamine as a treatment for dementia of the Alzheimer's type. 3) All negotiations of communications between Boehringer Ingelheim KG and Synpatech or Dr. Bonnie Davis regarding galanthamine as a treatment for dementia of the Alzheimer's type. 4) Information related to the November 8, 1989, letter from Prof. E. Muller, Department of Pharmacology, Boehringer Ingelheim KG, attached hereto as Exhibit 2 including without limitation the meaning of, basis for, and any evaluation or analysis concerning the statements set forth in the letter that "based on our extensive preclinical research data available to us, it is our feeling that this compound, while interesting from the point of view of its mechanism of action (acetycholinesterase inhibitor), does not have the biochemical and pharmacological profile which we consider essential for its potential use in the treatment of Alzheimer's disease." 5) Information related to the November 8, 1989, letter from Prof. E. Muller, Department of Pharmacology, Boehringer Ingelheim KG, attached hereto as Exhibit 2 including without limitation the meaning of, basis for, and any evaluation or analysis concerning the statements set forth in the letter that "[t]he limited clinical data (pilot study by Michael Rainer) are not very convincing." 6) Information related to the Confidentiality Agreement dated November 10, 1989, attached hereto as Exhibit 3. 7) Production of all documents relevant to (3) - (6) and deposition upon oral examination of Prof. E. Muller, Department of Pharmacology, Boehringer Ingelheim KG or a corporate representative of Boehringer Ingelheim KG; 8) Authentication of Exhibits 2 and Exhibit 3.

	b. Purpose of the evidence or judicial act sought	The purpose of this request for documents is to obtain trial evidence necessary to prove the validity of the '318 patent
9.	Identity and address of persons to be examined:	1) Prof. E. Muller, Department of Pharmacology, Boehringer Ingelheim KG 2) A corporate representative of Boehringer Ingelheim most knowledgeable to the issues set forth in Section 8.
	Requested time and place of examination:	Production of documents to be received by May 31, 2006. Deposition to occur at 9:00 a.m. at the U.S. Consulate in Frankfurt, Germany on June 14, 2006. Or such other date, time and/or venue as determined by the Court.
10.	Statement of subject matter about which the witness is to be examined:	Each of the individuals is to be examined about the following subject matter: 1) The names of all persons employed by Boehringer Ingelheim KG who were involved in any evaluation, performed: consideration of discussion to license, market or develop the '318 patent or a '318 patent product. 2) The names and responsibilities of all persons employed by Boehringer Ingelheim KG who were involved in any evaluation, consideration, or discussion of galanthamine as a treatment for dementia of the Alzheimer's type. 3) All negotiations of communications between Boehringer Ingelheim KG and Synpatech or Dr. Bonnie Davis regarding galanthamine as a treatment for dementia of the Alzheimer's type. 4) The November 8, 1989, letter from Prof. E. Muller, Department of Pharmacology, Boehringer Ingelheim KG, attached hereto as Exhibit 2 including without limitation the meaning of, basis for, and any evaluation or analysis concerning the statements set forth in the letter that "based on our extensive preclinical research data available to us, it is our feeling that this compound, while interesting from the point of view of its mechanism of action

(acetycholinesterase inhibitor), does not have the biochemical and pharmacological profile which we consider essential for its potential use in the treatment of Alzheimer's disease."
5) The November 8, 1989, letter from Prof. E. Muller, Department of Pharmacology, Boehringer Ingelheim KG, attached hereto as Exhibit 2 including without limitation the meaning of, basis for, and any evaluation or analysis concerning the statements set forth in the letter that "[t]he limited clinical data (pilot study by Michael Rainer) are not very convincing."
6) The Confidentiality Agreement dated November 10, 1989, attached hereto as Exhibit 3.

11. Documents or other property to be inspected:

It is requested that Boehringer Ingelheim KG produce the following documents for copying and inspection:

1) All negotiations of communications between Boehringer Ingelheim KG and Synpatech or Dr. Bonnie Davis regarding galanthamine as a treatment for dementia of the Alzheimer's type.
2) All Documents related to the November 8, 1989, letter from Prof. E. Muller, Department of Pharmacology, Boehringer Ingelheim KG, attached hereto as Exhibit 2 including without limitation the meaning of, basis for, and any evaluation or analysis concerning the statements set forth in the letter that "we have given serious consideration to the proposal of Waldheim Pharmazeutika to develop Nivalin (galanthamine) for the indication Alzheimer's disease."
3) All documents related to the November 8, 1989, letter from Prof. E. Muller, Department of Pharmacology, Boehringer Ingelheim KG, attached hereto as Exhibit 2 including without limitation the meaning of, basis for, and any evaluation or analysis concerning the statements set forth in the letter that "based on our extensive preclinical research data available to us, it is our feeling that this compound, while interesting from the point of view of its mechanism of action (acetycholinesterase inhibitor), does not have the biochemical and pharmacological profile which we consider essential for its potential use in the treatment of Alzheimer's disease."
4) All documents related to the November 8, 1989, letter from Prof. E. Muller, Department of Pharmacology, Boehringer Ingelheim KG, attached

		hereto as Exhibit 2 including without limitation the meaning of, basis for, and any evaluation or analysis concerning the statements set forth in the letter that "[t]he limited clinical data (pilot study by Michael Rainer) are not very convincing." 5) All documents related to the Confidentiality Agreement dated November 10, 1989, attached hereto as Exhibit 3.
12.	Any requirement that the evidence be given on oath or affirmation and any special form to be used:	It is required that the oral examinations be conducted under oath or affirmation. In the event that the evidence cannot be taken in the manner requested, it is requested that the evidence be taken in such manner as provided by local law for the formal taking of evidence.
13.	Special methods or procedures to be followed:	It is requested that the witness be placed under oath (or affirmation) that counsel for all parties be permitted to question the witness and that all questions and answers be transcribed by a shorthand typist as well as videotaped by a videographer. It is requested that insofar as it is not incompatible with the laws of Germany, the rules of procedure governing the taking of depositions in the United States by applied.
14.	Request for notification of the time and place for the execution of the Letter of of Request	Under Article 7, it is requested that notification be sent directly to each party's representative(s).
15.	Request for attendance or participation of judicial personnel of the requesting authority at the execution of the Letter of Request:	Not requested.
16.	Specification of privilege or duty to refuse to give evidence under the law of the State of Origin:	None.
17.	The fees and costs incurred which are reimbursable will be borne by:	ASHBY & GEDDES Steven J. Balick (Delaware Bar No. 2114) John G. Day (Delaware Bar No. 2403) 222 Delaware Avenue 17th Floor P.O. Box 1150 Wilmington, DE 19899

Telephone: 302-654-1888
Facsimile: 302-654-2067

18. Date of Request: ~~April~~ May 10, 2006

19. Signature and seal of the requesting Authority:

By the Court:

By: _____

United States District Judge for
the District of Delaware